POLICY AND COMMUNICATIONS BULLETIN
THE CLINICAL CENTER

Medical Administrative Series

M95-9 1 October 1995

MANUAL TRANSMITTAL SHEET

POLICY: Guidelines for Blood Drawn for Research Purposes in the Clinical Center

1. Explanation of Material Transmitted: This issuance combines and updates two policy statements dealing with obtaining blood from patients in the Clinical Center. The new policy originated in the Pediatric Care Committee, has been endorsed by the Quality Assurance Committee, and was approved by the Medical Board at its meeting on 5 September 1995.

2. Material Superseded: MAS 82-6 (reissue), dated 30 June 1989
and
MAS 88-1, dated 20 January 1988

3. Filing Instructions: "Other" Section

Remove: MAS 82-6 (reissue), dated 30 June 1989
and
MAS 88-1, dated 20 January 1988

Insert: No. M95-9, dated 1 October 1995

DISTRIBUTION

Institute Clinical Directors
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POLICY: Guidelines for Blood Drawn for Research Purposes in the Clinical Center

PURPOSE

This statement codifies the policy of the Medical Board regarding the drawing of blood for research purposes from adult and pediatric patients, including normal volunteers, in the inpatient units and outpatient clinics of the Clinical Center, and describes the procedures to be followed for obtaining specimens.

POLICY

Under most circumstances, the amount of blood that may be drawn from adults or children at the Clinical Center shall not exceed specified limits. These limits have been set by volume in the case of adults, and by body weight in the case of children.

The Clinical Pathology Department's Phlebotomy Service will draw bloods from outpatients in the course of routine patient care or for research purposes, according to the procedures set forth in this issuance.

CONSIDERATIONS

The IRB shall take cognizance of how much blood would be taken and with what frequency, consider the risks involved, and assure that the volume and frequency of collection, as specified in the protocol, are within safe limits. The Chief of the Clinical Center's Department of Transfusion Medicine may be consulted in cases of uncertainty.

Adult Patients and Volunteers

The amount of blood that may be drawn from adult patients and volunteers (i.e., those persons 18 years of age or older) for research purposes shall not exceed 450 ml. over any six week period. The amount of blood to be drawn from volunteers and the frequency of collection shall be specified in the clinical research protocol, and exceptions to the 450 ml. limitation shall be approved by the Institutional Review Board (IRB).

It should be noted that Federal regulations (45 CFR 46) place limits on the amount of blood that may be drawn for research activities that are subjected to expedited review. The restriction allows:

> "Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant."

If this particular restriction is not adhered to, the research is not eligible for expedited review.

Pediatric Patients

For pediatric patients, no more than 3 ml./kg. may be drawn for research purposes in a single blood withdrawal, and no more than 7 ml./kg. may be drawn over any six-week period. Investigators should consider further limiting blood drawing in patients with anemia or low cardiac output.

In instances of clinical needs, phlebotomy in excess of the above limits may be permitted if the patient has had his/her hemoglobin levels increased by transfusion.

Exceptions shall not be permitted for phlebotomy intended solely for research purposes unless the limits have been explicitly increased in a research protocol that has received full Institute IRB approval.

Record Keeping

Because blood samples in excess of those mandated by the protocol may be taken in the course of providing patient care, health care providers will assure that all instances of blood collection are recorded and justified in the patient's record.

PROCEDURES

General

The Clinical Pathology Department's Phlebotomy Service teams will draw bloods for tests listed on the Clinical Pathology Ordering Record (NIH Form 2353-1) or requested on a MIS Transmittal Request sheet. Research bloods will also be drawn by the phlebotomy team when requested on a Miscellaneous Blood Request Form (#557-106).

Specimens Required for Patient Care

A. Routine Specimens

1. The physician (or other authorized person) will complete the Tests (#2353-3) and Appointment Request (#293-2) forms.

2. The patient will take these forms to the unit clerk, who will complete the Clinical Pathology Ordering Record (#2353-1), if necessary, and schedule the ancillary tests and next clinical appointment.

3. The following information is required on all requests for outpatient laboratory services:

    a) Patient's name
    b) Patient's NIH hospital number
    c) Requesting physician's name.

4. The patient will be directed to the Outpatient Phlebotomy Service (ACRF, room 1C-249) with a Clinical Pathology Ordering Record (#2353-1) or a MIS Transmittal Request sheet.

5. Specimens to be drawn on Clinical Center outpatients will be taken only in patient care areas.

Other Specimens

1. The physician (or other authorized person) will complete the Ancillary Tests (#2353-3) and Appointment Request (#293-2).

2. For specimens other than routine, the name of the test will be written in the space marked "other" on the inside of the form or on a Miscellaneous Blood Request Form (#557-106).

3-5. See steps 2-4 above, under Routine Specimens.

Specimens Required for Research Purposes

1. Requests for research blood specimens must be made on a Miscellaneous Blood Request Form (#577-106) or in the comments section of the Clinical Pathology Ordering Record (#2353-1), and must contain the following information:

   a) Patient's name and NIH hospital number
   b) Requestor's name
   c) Volume of blood required.

2. Special instructions should be written on the Miscellaneous Blood Request Form (#557-106).

3. The investigator or the patient will bring appropriately labeled containers for the research blood specimen(s) to the Outpatient Phlebotomy Service (ACRF, Room 1C-249) before the scheduled appointment.

4. The volume of blood that will be drawn on a research patient shall not exceed the amounts given above for adult or pediatric subjects.

5. The only tests involving multiple venipunctures that are performed by the Phlebotomy Service are the glucose tolerance test (GTT) and thyrotropin-releasing hormone (TRH) test. Investigators ordering other tests requiring multiple venipunctures must submit a copy of the approved

protocol and a completed Phlebotomy Service Special Request Form (available in Room 1C-249) to the Chief, Clinical Pathology Department, for approval.

6. After the clinic visit, the investigator or designee will pick up the research specimens from the Outpatient Phlebotomy Service (ACRF, Room 1C-249). The Phlebotomy Service will not provide messenger service for these specimens.